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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,422	10/30/2003	Karl Cazzini	2527US	7224
26356	7590	10/18/2006	EXAMINER	
ALCON IP LEGAL, TB4-8 6201 SOUTH FREEWAY FORT WORTH, TX 76134			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,422

Applicant(s)

CAZZINI ET AL.

Examiner

david shay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 31, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “plurality of microbubbles displaced within the polymer matrix”; the “circular or semi-ellipsoidal incident surfaces”; “the optical cable comprises a plurality of optical fibers”; “the optical cable gauges is equal to the gauge of the optical fiber”; “the optical fiber is operatively connected to the handpiece to enable linear displacement of the optical fiber and the small gauge optical element within the cannula”; “the handpiece comprises a means for adjusting the linear displacement”; “the adjusting means comprises a push/pull mechanism”; “adjusting the linear displacement adjusts the small-gauge optical element position relative to the open aperture”; “the amount of linear displacement of the small-gauge optical element determines an angle of illumination and an amount of illumination”; “the angle of illumination can be varied between about 20 degrees to greater than about 180 degrees”; “one or more optical filters”; “the light source is a xenon or a halogen light”; “the plurality of microbubbles is randomly distributed”; “the plurality of microbubbles each have a diameter of about 1 to 50 microns”; and “the plurality of microbubbles is distributed with a distribution density operable to scatter and transmit the light beam in an isotropic manner” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure

must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant argues that the disclosure is sufficient to enable the person having ordinary skill in the art of wide angle illuminators to produce those items objected to by the examiner. The examiner must respectfully note that the question of the enablement has been raised and needs to be rebutted by material fact, not simple assertions. While the reference to pages 13-15 of the instant specification does contain certain discussions of manners in which the device may be made, there is, in the examiner's view, insufficient information to enable production of such a device. For example, with regard to the thermally expanding microsphere embodiment, it is unclear how any particular distribution (random, uniform, etc.) of the microspheres can be achieved. Similarly, with regard to both the expanding microsphere and the ultrasonic agitation embodiments, it is unclear what constitutes the "suitable curing conditions" that will produce the "spatial fixation" desired. And with respect to the microporous membrane, the manner in which a "viscous polymer/epoxy resin" is forced through a microporous filter in such a way as to mix any gas entrained therein is not clear, nor there is no provision for causing the microbubble to remain stationary in space throughout the storing and curing phases of this production process.

With regard to the indefiniteness rejection of claims 1-23, while applicant's arguments are noted, the examiner maintains that these claims are indefinite for the reasons stated. The specification indicates that only the microbubble laden material is the "optical element" and therefore, the optical fiber, cannula, etc. can form no part of this material, although they can clearly be used with it. Thus claiming these elements as part of the optical element also lends confusion to the interpretation of the term "optical element" as what this term is now intended to designate is not at all clear. Thus applicant's arguments are not convincing.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure does not enablingly describe how "plurality of microbubbles displaced within the polymer matrix"; the "circular or semi-ellipsoidal incident surfaces"; "the optical cable comprises a plurality of optical fibers"; "the optical cable gauges is equal to the gauge of the optical fiber"; "the optical fiber is operatively connected to the handpiece to enable linear displacement of the optical fiber and the small gauge optical element within the cannula"; "the handpiece comprises a means for adjusting the linear displacement"; "the adjusting means comprises a push/pull mechanism"; "adjusting the linear displacement

adjusts the small-gauge optical element position relative to the open aperture”; “the amount of linear displacement of the small-gauge optical element determines an angle of illumination and an amount of illumination”; “the angle of illumination can be varied between about 20 degrees to greater than about 180 degrees”; “one or more optical filters”; “the light source is a xenon or a halogen light”; “the plurality of microbubbles is randomly distributed”; “the plurality of microbubbles each have a diameter of about 1 to 50 microns”; and “the plurality of microbubbles is distributed with a distribution density operable to scatter and transmit the light beam in an isotropic manner” are achieved.

With regard to the claim sets 30-56 and 57-84, by way of clarification, the examiner has taken the liberty of assuming that applicant’s representative is sufficiently familiar with patent practice to understand that multiple claims of identical scope are improper. Given this knowledge, it is logical to assume that the two claim sets were drafted with the goal of providing two claim sets of differing scope. However, the difference in scope has to date eluded the examiner, thus what difference there is between the two independent claims of the sets (as an example) is unclear, thus the claims are indefinite, as exactly what they are trying to claim is unclear. While it is noted that according to applicant’s remarks, the two sets differ in the recitation of a light source, the examiner notes that as the preamble of each set of claims recites an “illuminator” and while applicant is not bound to recite every single element required to render the device functional (i.e. a power supply), these are still implicit in the claims (else the claims would be incomplete). Thus, since the illuminators would be incapable of illuminating, if there were no source of illumination, this structure is implicit in claims 30-56.

With regard to the rejection based on Hemphill, applicant asserts that Hemphill does not disclose a small gauge optical element including a polymer matrix having a plurality of microbubbles. The examiner notes that the lens of Hemphill is plastic (i.e. polymer, see column 1, line 20) wherein a blowing agent is mixed. This will produce a wide distribution of voids, some of which will be “microbubbles” the lens so produced is undeniably an optical element. While applicant has provided no definition of “small gauge” it, assuming that this particular preamble can be construed to “breath life and meaning” into the claim language (something the examiner does not concede) it can be seen that the lens is of minimal thickness (and in fact will be made as thin as possible, to reduce costs) and as such can be considered “small gauge”.

As to the combination rejection, applicant argues that since Turner does not disclose the entirety of the claimed invention, there is no motivation to combine Turner with any other reference. The examiner must respectfully point out that this is not the basis upon which the determination of a proper combination under 35 USC 103 is made. The examiner notes that Bahmanyar et al, which is concerned with the field of ophthalmic light applicators, expressly teach that “ball diffractive, holographic, microlenslets, or any combination thereof” are equivalents in the art and this is sufficient motivation to combine these references. Further, Knowles et al teach that microbubbles act as microlenses, as already set forth. Thus the use of microbubbles, as the microlens material, would be obvious, given that this would require the use of an additional material, but merely the production of bubbles in the polymer, thereby requiring less expense to produce each device. Thus applicant’s contention that the references are not combinable, and even if combined would not produce the claimed invention, are noted, but are not convincing.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23, 49, 50, 77, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-29 are indefinite because the preamble of the claim is of a different scope than the body thereof, in that the preamble merely recites an optical element and the body of the claim recites for example such elements as an optical fiber; optical cable; cannula; and light source, which are not properly parts of the optical element. Claims 22, 23, 49, 50, 77, and 78 are indefinite as they fail to further limit the claim from which they depend, as they recite the surgical environment, which is not properly part of the device and therefore what further limitation is intended to be implied is unclear. Claims 30-56 and 57-84 are indefinite because what the differences is between these claim sets is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hemphill.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 22-38, 49-66, and 77-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in combination with Bahmanyar et al and Knowles et al. Turner teaches a device as claimed except for the use of microlenses per se; a circular or semi-ellipsoidal surface; the optical cable comprising two SMA connectors; the microlenses being 1 to 50 microns in diameter; and the optical element being 2 millimeters long. Bahmanyar et al teach the equivalence of microlenses and holographic elements, the use of connecting cables with multiple fibers and two SMA connectors. Knowles et al teach that microbubbles function as microlenses. It would have been obvious to the artisan or ordinary skill to employ microlenses in the place of the holographic element of Turner, since these are equivalents, as taught by Bahmanyar et al; to form the microlenses as microbubbles, since microbubbles are known in the art of optics to behave in this manner, as taught by Knowles et al, and to form the optical element to have a circular or semi-ellipsoidal surface, to be 2 millimeters long, so as to not unduly enlarge the device, and to have microbubbles between 1 micron and 50 microns in diameter, so as to render the microbubbles small enough to enable the light beam to interact with a large number of them, and since all these features are well known in the art; are well within the scope of one having ordinary skill in the art, and provide no unexpected result, thus producing a device and method such as claimed.

Claims 12-18, 39-45, and 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in combination with Bahmanyar et al and Knowles et al as applied to claims 1-11, 22-38, 49-66, and 77-84 above, and further in combination with Pankratov et al. Pankratov et al teach a device with a fiber that is longitudinally translatable to change the size of

the illuminated area. It would have been obvious to the artisan of ordinary skill to provide the linear displacement means of Pankratov et al in the device of Turner, since this would allow the illuminated area to be changed much more rapidly than by the optical element switching technique of Turner, which would require the device to be withdrawn from the eye, thus providing a shorter operation, which is desirable as it reduces the amount of stress on the physician and patient, official notice of which is hereby taken, and to situate the distal end of the optical element so as to be coincident with the distal end of the cannula, as this is well within the scope of one having ordinary skill in the art, maximizes the light output, and provides no unexpected result and to allow the angle of illumination to be varied between about 20 degrees to greater than about 180 degrees, as this is well within the scope of one having ordinary skill in the art, would allow a wide variety of surgical fields to be illuminated, and provides no unexpected result, thus producing a device such as claimed.

Claims 19-21, 46-48, and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in combination with Bahmanyar et al and Knowles et al as applied to claims 1-11, 22-38, 49-66, and 77-84 above, and further in combination with Fritch et al. Fritch et al teach the use of filters and a broad band light source to provide illumination for ocular surgery. It would have been obvious to the artisan of ordinary skill to employ the broad band illuminating source and filters of Fritch et al in the device of Turner, since Turner discloses no particular source, and to employ a xenon or halogen lamp, since these are well known for use in ophthalmic devices, as they provide bright light, official notice of which is hereby taken, thus producing a device such as claimed.

Applicant's arguments filed July 31, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. M. Shay' with a stylized flourish at the end.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330